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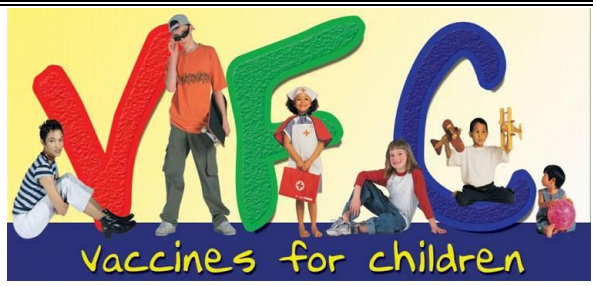
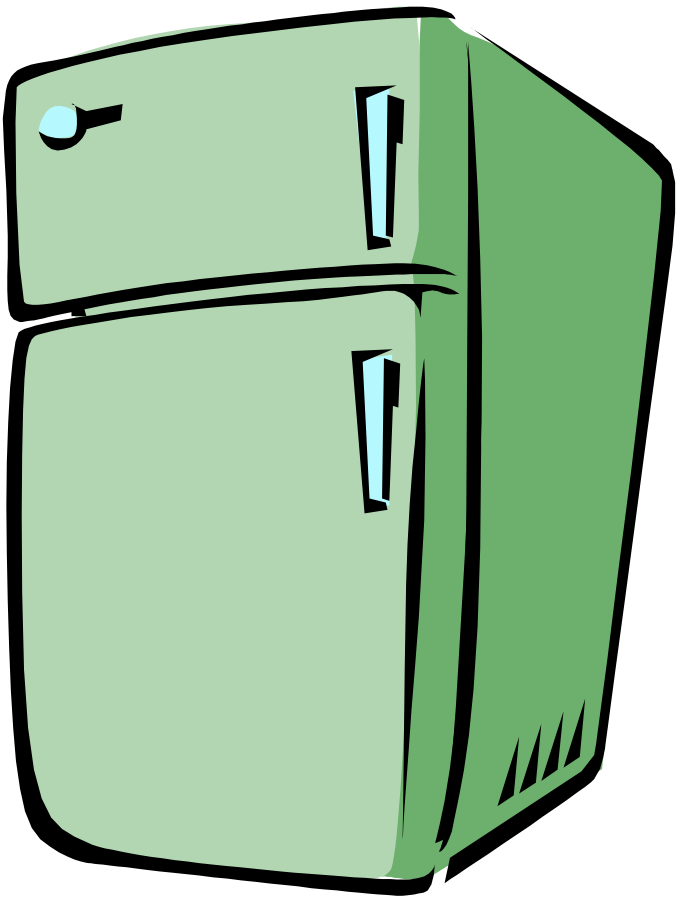
Department of Public Health & Human Services

Immunization Program



Refrigerator/Freezer Guide to Vaccine Storage



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Introduction

Vaccines are expensive and fragile, and storing them at the proper temperature is essential to providing effective immunizations. The Centers for Disease Control and Prevention (CDC) and the Montana Immunization Program require Vaccines for Children (VFC) providers to have reliable storage equipment that can store vaccines under proper conditions.

The following information outlines the storage unit requirements of the Montana VFC Program. Forms mentioned in this guide can be found at www.immunization.mt.gov or contact the Montana Immunization Program 444-5580. For a comprehensive look at VFC vaccine management, please refer to your *Vaccine Management Plan*.

General Requirements

Refrigerators and freezers used for storing VFC vaccine must comply with the following requirements (*VFC Operations Guide*, M-6, pg.8):

- Be able to maintain required vaccine storage temperatures year-round:
  - Refrigerator: 2° to 8°Celsius (C) (35° to 46° Fahrenheit (F))
  - Freezer: -15°C or colder (5°F or colder)
- Be large enough to hold the year's largest inventory plus ice packs (freezer) and water bottles (refrigerator) to stabilize temperatures
- Have a working NIST- or ASTM-calibrated thermometer inside each storage compartment
- Be dedicated to vaccine storage (i.e., food and beverages are not allowed in vaccine storage units.)

Storage Units

Combined versus Stand-Alone Units

Two types of storage units are acceptable:

- Combined refrigerator/freezer units that have separate external doors for each compartment
- Stand-alone refrigerators and freezers

Combined units are those that have a refrigerator and freezer compartment in one appliance. Stand-alone units have just one compartment that is either a refrigerator or freezer. In general, stand-alone units are a better choice for vaccine storage than combined units.

Combined units control the refrigerator temperature by diverting cold air from the freezer through a vent or fan. The temperatures in the two compartments are "linked," and an adjustment in one can drastically affect the temperature in the other. This makes stabilizing the temperature in each compartment difficult. Combined units can also experience localized areas of freezing temperatures in the refrigerator especially near where cold air comes in from the freezer. These characteristics of combined units can cause vaccine in the refrigerator to freeze. Stand-alone units avoid these problems by only being required to hold a single temperature and not "sharing" air between compartments.

Despite their limitations, combined units can be used to store VFC vaccine as long as you take the following precautions:

- Follow the vaccine placement guidelines on page 8 to maximize air flow and prevent freezing temperatures in the refrigerator compartment (See *Vaccine Placement* page 8).
- Adjust temperatures carefully by following the guidelines in the *Temperature Monitoring* section on page 9.

Dormitory-Style Storage Units

Dormitory-style (also called "bar-style") refrigerator/freezer units are those where the freezer is contained within the refrigerator, and both are accessed by one external door. Please note that the term "dormitory-style" does not refer to the size of the unit. It refers to the placement of the freezer within the refrigerator compartment. These units cannot reliably maintain vaccine storage temperatures. The CDC prohibits the use of dormitory-style storage units for the permanent storage of VFC vaccine.

Figure 1 Dormitory-Style Refrigerator/Freezer

The Montana Immunization Program Policy on Dormitory-Style Storage Units:

- Beginning with the 2011 re-enrollment, which occurs in April, VFC providers are prohibited from using dormitory-style storage units for permanent storage of VFC vaccine.
- Permanent storage is defined as that involving more than one day's supply of vaccine for longer than one daily work shift (12 hours).
- The practice of using dormitory-style units for *temporary* storage of VFC vaccine is allowed for those providers already using the units in this capacity (as of February 1, 2011) and as long as certain conditions are met.
- Temporary storage is defined as that where only one day's supply of vaccine is stored for one work day (no more than 12 hours). Vaccine is returned to permanent storage at the end of the day.
- Providers wishing to continue to use dormitory-style units for temporary storage of VFC vaccine must agree to certain conditions and get written approval from the Montana Immunization Program. Please contact the Immunization Program for more information.
- VFC vaccine storage units acquired for VFC vaccine after February 1, 2011 must not be dormitory-style units regardless of whether they are used for temporary or permanent storage.

Grade or Quality

Domestic Grade

Domestic (or "household") quality storage units are those typically found in homes and sold at retail appliance store. Domestic grade appliances can be used to store VFC vaccine as long as combined refrigerator/freezer units have a separate external door for the refrigerator and freezer compartments (See *Dormitory-Style Units* above).

Other desirable features include:

- Separate temperature controls for refrigerator and freezer
- Automatic defrost cycling (i.e., "frost-free")
- Fully adjustable shelves
- Door locks
- Door ajar alarm
- Battery back-up

Features to avoid:

- Manual defrost units – These units accumulate frost and ice on the walls of the freezer and cooling coils, and require periodic "defrosting." If you have a manual defrost unit you must arrange alternate vaccine storage and temperature tracking while you defrost your appliance.

- Single-temperature control units – These are combined units with a single thermostat dial that controls both the refrigerator and the freezer. This configuration makes it difficult to maintain appropriate temperatures in both compartments and increases the likelihood of freezing vaccine in the refrigerator. **Please note** that The Montana Immunization Program does not prohibit the use of single-thermostat units. However, such units should be monitored carefully. If temperature excursions and vaccine wastage occur, you will be required to upgrade to a dual temperature control model.

Laboratory/Pharmacy Grade

Laboratory or pharmacy grade refers to storage units that are specifically designed to store vaccine and pharmaceuticals in a laboratory or pharmaceutical setting. These are the highest quality option for storing VFC vaccine. Laboratory grade appliances come with safety, temperature control, and security options typically not found on domestic units. Although usually more expensive, they come in a wide variety of sizes, configurations, and prices, including moderately price under-counter models ideally suited for small clinics.

Size Determination

Your VFC vaccine storage unit must be able to store the year's largest supply of vaccine including ice packs and water bottles used to stabilize temperatures. It also must be large enough to allow spacing between vaccine packages for proper air circulation (See *Vaccine Placement* pg. 8).

To determine the size storage unit you need, calculate separately for your refrigerator and freezer the largest number of doses you will have on hand during the year. Be sure to include seasonal influenza and private stock if it will all be stored in the same unit. Multiply the maximum doses by 1.25 to account for package spacing. This gives your maximum doses. Use this number and the charts below to determine the minimum cubic feet of storage space you will need.

Table 1 Minimum Cubic Feet of Storage Space Based on Maximum Doses

Maximum Doses	Minimum Cubic Feet Refrigerator Space
1001–2000	40
900–1000	36
801–900	21–23
701–800	17–19.5
401–700	11–16.7
100–400	4.9–6.1

Maximum Doses	Minimum Cubic Feet Freezer Space
501–6000	7–14.8
201–500	5–5.6
0–200	3.5–4.9

Setting up your Storage Unit

Follow the procedures below when acquiring a new storage unit, moving an existing unit, or reestablishing a unit after a power outage or repair.

Unit Placement

- Place the unit close to a reliable electrical outlet (See *Electrical Supply* below).
- For proper cooling and heat exchange, locate the storage unit in a well-ventilated space away from direct sunlight and with 4 inches between the unit and surrounding walls, cabinets, and appliances.
- Do not block the motor compartment, which is usually located in the back or side of the unit.

Electrical Supply

- Place the storage unit near enough to an outlet so that the cord is not a tripping hazard and an extension cord is not necessary.
- Make sure the outlet is not controlled by a light switch.
- Place a “DO NOT UNPLUG” sign next to the outlet ***and its controlling circuit breaker***. If these are not accessible or visible, place the sign as near as possible so that people accessing the outlet or circuit breaker are likely to see it.

- If possible, do not plug more than one appliance into the outlet to avoid tripping the circuit breaker.
- If you have a backup power supply for your facility, make sure it is in working order and tested regularly.
- If you do not have a backup power supply, arrange at least one alternate vaccine storage location that has proper refrigerator and freezer units, temperature monitoring capability, and backup power where your vaccine can be moved in the event of a power outage. Record this information in your *Vaccine Management Plan*.

Temperature Stabilizing

- Plug the unit into the electrical outlet and set the temperature to fall within the following ranges:

  Refrigerator: 2° to 8°C (35° to 46°F)

  Freezer: -15°C or colder (5°F or colder)

  - If the unit has a thermostat, set to the following target temperatures:
    - Refrigerator: 4°C or 40°F
    - Freezer: -20°C or -5°F
  - If the unit has a controller with numbers or words (e.g., “colder”), set as follows:
    - Refrigerator: Set slightly below the mid-range.
    - Freezer: Set to mid-range.
    - **Please note –** For most numbered temperature dials, the higher the number the colder the temperature. Check your owner’s manual to avoid improper adjustments.
- Place a working NIST- or ASTM-calibrated thermometer inside each storage compartment in a central location away from walls, vents, fans, and cooling coils. The Montana Immunization Program has a supply of thermometers for VFC providers.
- Place several containers of water along the inside walls, in door racks, and vegetable bins (“crispers”) of the refrigerator, and several frozen packs along the walls and in the door rack of the freezer. These will help stabilize temperatures when the door is open and in the event of a power outage. Do not over-fill with water bottles and ice packs such that air flow is impeded.
- Make sure doors close tightly and seals are intact.
- Allow the unit to stabilize overnight and check temperatures in the morning.
- Adjust the dial or thermostat until the target temperature is achieved and held for at least 3 days. Log temperatures at least twice a day during the adjustment period.
- Once the temperature is in range and stabilized, your storage unit is ready to receive vaccine.

Vaccine Placement

- Place vaccine in the middle of the compartment away from ceilings, walls, vents, fans, and coils. In combined units, keep vaccine away from the vent or fan channeling air from the freezer.
- Never store vaccine in door racks or vegetable bins. Consider removing vegetable bins to facilitate air circulation. This will provide more space for water containers.
- Clearly label vaccine “VFC” and keep it physically separated from private stock.
- Keep vaccine in its original packaging and organize by vaccine type. Consider physically separating vaccines with similar names, packaging, or antigens to avoid administration errors.
- Organize packages so that short-dated vaccine is used first.
- If containers are used to organize vaccine, use only open containers with walls that allow air to circulate, such as wire baskets.
- Never store food or beverages in vaccine storage units. Other biologicals can be stored in vaccine storage units as long as they are physically separated from vaccine to prevent contamination and administration errors.
- Diluent packaged with the vaccine should be stored at the same temperature as the vaccine. Diluent packaged separately from the vaccine can be stored refrigerated or at room temperatures.

Temperature Monitoring

- Monitor temperatures twice a day on vaccine storage units. This is required even if your unit has a continuous monitoring chart/logger, or a temperature alarm.
- Document the twice daily temperature readings on a form that clearly indicates the date and time of the reading, the initials of the person taking the reading, acceptable temperature ranges, and what to do when temperatures are out of range. The Montana Immunization Program can provide temperature logs that meet these requirements. Temperature logs must be kept for 3 years and made available during clinic reviews.
- Temperature adjustments should be done by the clinic’s Vaccine Coordinator or Alternate Vaccine Coordinator only. Consider posting a sign discouraging temperature adjustments by unauthorized personnel.
- DO NOT adjust temperatures in the evening or before a weekend when temperatures cannot be monitored.

- When adjusting temperatures, make slight changes to the thermostat or temperature dial and allow the unit to stabilize for 30 minutes. (Check your owner's manual to make sure controller adjustments are in the proper direction.) Check and record the temperature.
- Repeat, until the temperature is comfortably within range and stable.
- Record all temperature adjustments and issues with your storage unit on a Vaccine Storage Trouble-Shooting Record. Logging these events will communicate vaccine storage issues to all staff, and document recurring problems and trends with your unit. This will help catch minor problems early before they lead to major incidents that waste vaccine.
- Be proactive in addressing storage unit issues before they result in vaccine wastage.

Out-of-Range Temperatures

- If vaccine is exposed to out-of-range storage temperatures, follow the instructions on the Vaccine Incident Report. This document can be found at www.immunization.mt.gov under the VFC link.